

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

In re GILEAD SCIENCES SECURITIES
LITIGATION,

No. C 03-4999 SI
No. C 03-5088 SI
No. C 03-5113 SI
No. C 03-5391 SI
No. C 03-5592 SI
No. C 03-5805 SI
No. C 04-0100 SI

This document relates to all actions.

**ORDER GRANTING IN PART AND
DENYING IN PART DEFENDANT'S
MOTION TO DISMISS FOURTH
CONSOLIDATED AMENDED CLASS
ACTION COMPLAINT WITH LEAVE
TO AMEND**

Defendants have filed a motion to dismiss the fourth consolidated amended class action complaint. The motion is scheduled for a hearing on June 5, 2009. Pursuant to Civil Local Rule 7-1(b), the Court determines that the matter is appropriate for resolution without oral argument, and VACATES the hearing. For the reasons set forth below, the Court GRANTS in part and DENIES in part the motion and GRANTS plaintiffs leave to amend. Plaintiffs shall file an amended complaint by **June 26, 2009**. The Court will hold a case management conference on **July 17, 2009** at 3:00 pm.

DISCUSSION¹

Defendants contend that the fourth consolidated amended complaint ("FAC") fails to adequately plead falsity, scienter, and materiality. Defendants contend that these deficiencies doom plaintiffs' first

¹ The background of this case is familiar to all the parties and has been recounted in numerous orders, including the recent Ninth Circuit decision *In re Gilead Sciences Securities Litigation*, 536 F.3d 1049 (9th Cir. 2008), and thus will not be repeated here.

claim for relief for a violation of Section 10(b) of the Exchange Act of 1934, as well as the second claim for relief for a violation of Section 20(a) of the same act. Defendants raise numerous grounds for dismissal in their motion, including the overarching question of whether the complaint's reliance on two confidential informants meets the standards enunciated in *Zucco Partners, LLC v. Digimarc Corporation*, 552 F.3d 981 (9th Cir. 2009). In *Zucco*, the Ninth Circuit instructed "the confidential witnesses whose statements are introduced to establish scienter must be described with sufficient particularity to establish their reliability and personal knowledge," and "those statements which are reported by confidential witnesses with sufficient reliability and personal knowledge must themselves be indicative of scienter." *Id.* at 995.

The gravamen of the FAC is that defendants engaged in an illegal marketing scheme whereby they falsely reported that sales of the company's most popular product, Viread, were driven by strong demand, when in fact those sales were attributable in large part to illegal "off-label" marketing of the drug. The FAC relies on several types of factual allegations to plead scienter, including (1) statements of two confidential witnesses; (2) a March 14, 2002 "Untitled FDA Letter"; (3) a July 29, 2003 "FDA Warning Letter"; (4) other anonymous sources described in the FAC as, for example, "Infectious Disease Specialist in the Southeast United States" "Medical Director of a large AIDS clinic in Washington, D.C.," and "AIDS specialist from the Western United States" who state that Gilead sales representatives marketed Vilead for off-label purposes; (5) press releases discussing revenues and sales of Viread; and (6) the individual defendants' sales of stock during the class period. The only basis for the FAC's allegations that 75% to 95% of Viread's sales during the class period were "off-label" is information provided by the two confidential witnesses.²

Defendants contend that the two confidential witnesses lack sufficient indicia of reliability. Defendants assert that CW2 is unreliable because although the FAC alleges that "CW2 estimates that 85%-90%" of his or her sales were the result of off-label marketing, FAC ¶¶ 148-49, 163, a previous

² The allegations about off-label marketing to doctors state that such marketing occurred prior to the class period, or do not specify a time-period. *See e.g.*, FAC ¶¶ 156, 159. The FAC also cites studies showing that many patients with HIV were taking Viread as a "first-line" treatment for which it had not been approved. These allegations support plaintiffs' claim that defendants engaged in a scheme to market Viread for off-label uses. However, these allegations are not equivalent to an allegation that defendants engaged in significant off-label sales of Viread during the class period.

1 version of the complaint alleged that “despite his or her superiors’ pressure to market Viread using off-
2 label materials, CW2 refused.” CAC ¶ 50 (Consolidated Amended Complaint, filed April 30, 2004,
3 Docket No. 50).³ Defendants argue that it was only after Judge Jenkins dismissed the CAC that
4 plaintiffs amended CW2’s allegations to state that CW2’s sales were largely driven by off-label
5 marketing. Defendants argue that the complete reversal on a central point renders CW2 unreliable.

6 In response, plaintiffs contend that the Court cannot weigh the credibility of witnesses on a
7 motion to dismiss. Plaintiffs also assert that “any clarification of earlier pleadings may not be used to
8 challenge CW2’s credibility because the Court may only focus on the FAC, the pleading currently before
9 this Court.” Opposition at 15 n.18. Plaintiffs also assert that they have sufficiently described CW2 with
10 particularity, and that CW2’s allegations are corroborated by other allegations, such as the FDA letters,
11 the allegations of CW1, and statements by other anonymous medical practitioners who state that Gilead
12 sales representatives marketed off-label uses of Viread to them.

13 However, contrary to plaintiffs’ assertion that the FAC “clarified” earlier pleadings, the new
14 allegation in the FAC that 85% to 90% of CW2’s own sales of Viread were off-label directly contradicts
15 the CAC’s allegation that CW2 refused to make off-label sales. Neither the FAC nor plaintiffs’
16 opposition provides any explanation for the change in CW2’s allegations. While the Court agrees with
17 the general proposition that “clarifications” in pleadings do not necessarily render those pleadings
18 suspect, here the amendment was material and without explanation. Judge Jenkins dismissed the CAC
19 because, *inter alia*, plaintiffs had not established a connection between the company’s off-label
20 marketing activities and the 2003 second quarter reports that plaintiffs alleged were false and
21 misleading. Order at 12 (Docket No. 159). Judge Jenkins noted that “Plaintiffs have not alleged that
22 any sales of Viread during the second quarter of 2003 were the result of improper off-label marketing
23 activities,” and that “even assuming Plaintiffs had alleged that such sales took place, Plaintiffs would
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28 ³ In the CAC as in the FAC, CW2 alleged that he/she had attended various meetings at which
Gilead’s sales and marketing team received specific instructions to market Viread off-label.

1 also have to allege that those sales were ‘material’ to the 2003 second quarter reports.” *Id.* at 13.⁴ Not
 2 only did the FAC allege for the first time off-label sales of Viread during the second quarter of 2003,
 3 but also that such sales – attributable to CW2 – were significant. FAC ¶ 148 (alleging prior to class
 4 period, 85%-90% of CW2’s sales were off-label based on total of between \$10 and \$15 million; between
 5 late 2002 and early 2004, 85%-90% of CW2’s sales were off-label, based on total of between \$15 and
 6 \$20 million).⁵

7 Plaintiffs cite several cases in support of their assertion that the Court cannot weigh the
 8 credibility of a witness on a motion to dismiss. The Court agrees that the general credibility of CW2
 9 is a matter for determination at a later stage in the proceedings. However, the Ninth Circuit has
 10 repeatedly emphasized the importance of ensuring the reliability of confidential witnesses. *See*
 11 *generally Zucco Partners*, 552 F.3d at 995-99; *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1015 (9th
 12 Cir. 2005). Particularly where, as here, the amendment flatly contradicts earlier pleadings, and where
 13 the confidential witness is one of only two sources of information about off-label sales during the class
 14 period, the Court is unable to find on this record that CW2’s allegations about off-label sales during the
 15 class period are reliable.

16 Defendants challenge CW1 on several grounds. First, defendants contend that this witness is
 17 unreliable because he/she left Gilead several months before the class period. The FAC alleges that CW1
 18 worked at Gilead from 2001 until approximately May 2003. FAC ¶ 40. Defendants contend that, as a
 19 result, CW1’s allegations about off-label sales during the class period are speculative. The Court agrees.
 20 *See Zucco Partners*, 552 F.3d at 996 (two confidential witnesses who were not employed during the
 21 class period “have only secondhand information about accounting practices at the corporation during
 22 that year”); *Brodsky v. Yahoo! Inc.*, 592 F. Supp. 2d 1192, 1202 (N.D. Cal. 2008); *Shurkin v. Golden*

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 24 ⁴ Plaintiffs emphasize Judge Jenkins’ statement in the same order that “when the allegations of
 25 CW1 and CW2 [that Gilead representatives were instructed to engage in off-label marketing] are
 26 considered in light of the FDA’s letters to Gilead, it becomes apparent that Plaintiffs have alleged
 27 sufficient facts to raise a strong inference that Defendants had knowledge of the company’s off-label
 28 marketing scheme.” Order at 12. The Court agrees that similar allegations in the FAC raise the strong
 inference that defendants were aware of the illegal off-label marketing. The current deficiency lies in
 the allegations of off-market sales during the class period.

⁵ The asserted class period is between July 14, 2003 and October 28, 2003, inclusive. FAC ¶
 1.

1 *State Warriors*, 471 F. Supp. 2d 998, 1015 (N.D. Cal. 2006) (“CW3’s employment ended before the
2 Class Period and thus, CW3 lacks any personal knowledge as to the GSV’s production activity during
3 the 2Q04 that is at issue here.”). The Court does not discount CW1’s allegations about his/her own
4 experiences, such as sales prior to the class period, or meetings that CW1 attended. However, any
5 information CW1 has about sales during the class period is necessarily secondhand and thus “does not
6 provide the requisite particularity to establish that certain statements of [this] confidential witness[] are
7 based on the witness[’es] personal knowledge.” *Zucco Partners*, 552 F.3d at 996.

8 Second, defendants contend that there is no corroborative evidence supporting CW1’s
9 allegations. To the extent that CW1’s allegations are based on hearsay, those allegations lack reliability.
10 *See Zucco Partners*, 552 F.3d at 997. However, the Court disagrees with defendants’ broader assertion
11 that the Court should disregard all of CW1’s allegations, as the FAC alleges in detail numerous meetings
12 that CW1 (and CW2) attended at which Gilead sales and marketing personnel were instructed to
13 promote off-label uses of Viread, including a meeting attended by numerous individual defendants.

14 Accordingly, the Court GRANTS plaintiffs leave to amend to add further support to allegations
15 of off-label sales during the class period. Plaintiffs may cure this deficiency by adding additional
16 confidential witnesses who allege that there were off-label sales of Viread during the class period, and/or
17 by providing an explanation of the change in CW2’s allegations on this point.

18 The Court is not persuaded by the other contentions raised in defendants’ motion to dismiss.
19 Defendants contend that the FAC does not adequately allege falsity and that defendants had no duty to
20 disclose the alleged off-label marketing. Defendants argue that all of the press releases regarding sales
21 and revenue were factually accurate, and they emphasize that Gilead met forecasted revenue. However,
22 “a statement that is literally true can be misleading and thus actionable under the securities laws.” *Brody*
23 *v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) (citing *In re GlenFed Sec. Litig.*, 42
24 F.3d 1541, 1551 (9th Cir. 1994)); *In re Amgen Sec. Litig.*, 544 F. Supp. 2d 1009, 1034 (C.D. Cal. 2008)
25 (plaintiffs sufficiently alleged false and misleading statements where, even though disclosures were
26 literally accurate, plaintiffs alleged that defendants “promoted unapproved uses and increased
27 per-patient dosages through improper means [and] [t]hus, Defendants misled investors by implicitly and
28 falsely warranting that there were no illegal practices contributing to that success.”). For the same

1 reasons, the Court finds that the FAC sufficiently pleads materiality of the alleged omissions and
2 misstatements. *See also In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1405 (9th Cir. 1996) (“The
3 ‘materiality’ of an omission is a fact-specific determination that should ordinarily be assessed by a jury
4 [and] [O]nly if the adequacy of the disclosure or the materiality of the statement is so obvious that
5 reasonable minds could not differ are these issues appropriately resolved as a matter of law.”). Finally,
6 the Court finds that the FAC adequately pleads a basis for holding the individual defendants liable. *See*
7 *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782 (9th Cir. 2008).

9 CONCLUSION

10 For the foregoing reasons, the Court GRANTS defendants’ motion to dismiss the fourth
11 consolidated amended complaint and GRANTS plaintiffs leave to amend the complaint. (Docket No.
12 211). The amended complaint must be filed no later than **June 26, 2009**.

14 **IT IS SO ORDERED.**

16 Dated: June 3, 2009



SUSAN ILLSTON
United States District Judge